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Name of Invention: Manufacturing Method for a Catheter

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SPECIFICATION

1. Name of the Invention

Manufacturing Method for a Catheter

2. Claims

The manufacturing method for a catheter characterized by its main composition of rubber or plastic, with a silver film, covering over at least the portion which would be inserted into a human cavity, produced by silver mirror reaction on both sides of the surfaces which have been semi-hardened by a hardening treatment.

3. Detailed Explanation of the Invention

(Areas of Industrial Utility)

This invention relates to a catheter consisting of a thin silver film with a bactericide or bacteria reducing ability on the wall surfaces of medical catheter which is used to remove fluid from a body cavity or inversely, to inject fluid into a body cavity; specifically a urinary canal catheter which is inserted into a bladder through a urinary canal.

(Conventional Technology)

During cerebro-spinal illnesses such as cerebral hemorrhage, softening of brain and damage to the spine, difficulty to urinate or loss of ability to urinate occurs. At this time the insertion of a urinary catheter into the bladder in order to void urine becomes necessary. Moreover, post-operative patients requiring not only to void urine, but also to remove accumulating fluid and pus from body cavities are often fitted with various catheters which

may b left in these cavities.

The main problem, when a catheter is left in a body cavity, is inf ction by bacteria. It is sp cially true for a urinary catheter due to its long resident time in the urinary canal where bacteria adhering to anus and sexual organs can infiltrate through the tubing into the bladder causing urinary canal infection. Especially in the case of women whose urinary canals are wide and short, and at the same time straight as compared to men's, the bacterial infection rate is extremely high.

In order to prevent this bacterial invasion into the bladder, a known conventional solution is to attach a metallic ring or coil with bactericide or bacteria reducing ability to the body of the tubing used in a catheter. (Refer to Patent Publication ⁄54-14876.)

However, with the previously mentioned method of attaching a metallic ring or coil, the catheter becomes wider in areas of the tubing due to the thickness of the metallic ring, etc., causing increased pain to patients at the time of insertion in addition to the extreme difficulties in maintaining the position of the ring on the catheter tubing.

(Problems This Invention Is Designed to Solve)

This invention eliminates the above mentioned problems associated with the conventional catheter, and offers a catheter which can be inserted without pain to patients, but also a catheter that retains a long term effectiveness for infection prevention at an extremely low cost.

(Procedure to Solve the Problems)

In order to reach the goals specified above, this invention is characterized by its use of rubber or plastic as its main composition for the catheter; by hardening to a semi-hardened condition at least the portion of the catheter which would enter human body cavities; by treatment of this semi-hardened surface with silver mirror reaction until the surface is covered with a thin silver film; and by additionally hardening the semi-hardened portion to a desired hardness.

(Reaction)

This invention describes a catheter with its tubing or at least the portion of the tubing which goes into a body cavity, which has been treated with silver mirror reaction enabling to form an extremely thin silver film with a bactericide or bacteria reducing ability; thus the tubing portion of the catheter does not become thick and wide (Even when it attaches to the inside wall of the tubing, the inside diameter does not decrease.). Moreover, the silver mirror reaction takes place on rubber or plastic of the body of a catheter; specifically, the silver mirror reaction is performed on at least the semi-hardened portion of the catheter tubing to form a thin silver film; then the portion with the silver film attached is further hardened; thus, silver penetrates into the resin, and cannot easily fall off, to enable a long term emission of silver ions.

Therefore, the catheter described herein does not differ in thickness as frequently the commercially available rubber or

plastic catheters do, and by having an extremely thin silver film, there is no pain to each patient at the time of insertion as compared to the catheters with th previously mentioned metallic rings, etc., in addition to its ability to prevent infection, the catheter of this invention can be left in a body cavity for a long duration of time without inducing infection.

Moreover, this invention offers the advantage in easily utilizing rubber, which conventionally is not used nude due to its harmful nature to humans, as the base ingredient for a catheter without the necessity of teflon coating the surfaces of rubber parts, because the metallic film which is non-toxic to humans is attached to at least the portion which goes into a body cavity through non-electrolytic plating treatment.

Below is the detailed explanation of this invention.

The catheter tubing constructed with rubber or plastic was treated with heat to the semi-hardened state; after masking this semi-hardened catheter tubing leaving only the portion to be treated with silver mirror reaction, the silver is attached with silver mirror reaction treatment, then the entire unit is hardened to a desired hardness with a heat treatment. By treating the semi-hardened catheter itself with silver mirror reaction followed by the final hardening, the silver film introduced to the surface of the catheter adheres tightly onto the resin, avoiding peeling then or at the time of catheter usage.

Depending on the choice of resin which makes up the catheter itself, the adhering ability of silver after silver mirror reaction

treatment may be low. In this case, semi-hardened catheter material should be soaked in catheter surface treatment solution - alkaline solution (for example, NaOH, KOH) more than 1 normal but less than 10 normals and more than 5 v o 1 % but less than 50 v o 1 % alcohol (for example, ethanol, propanol) and Q. S. with water - to induce hydrophilic groups on the surface of the catheter tubing followed by the silver mirror treatment. The reason for the limits put on the concentrations of alcohol and alkaline is that when both of these materials are too low, then the incorporation of hydrophilic groups becomes incomplete and when both of these materials are too high, there is a possibility of resin deterioration.

Moreover, the hole between the tip of the catheter itself to

the inside of the tubing does not have to be masked when silver mirror treatment is conducted; it is obvious that the silver film is formed in the inside wall of the catheter itself.

(Working Example 1)

After constructing the catheter with crude rubber, it was semi-hardened to about 60% with a heat treatment. To this catheter in a semi-hardened condition, silver bromide 20 g and an appropriate amount of ammonium hydroxide were added, to this solution 100 g of potassium sodium tartrate and enough water to make the total volume 1700 ml were added to make silver mirror reaction treatment solution to form a silver film of about 0.2 um thickness on the surface of the catheter. The catheter thus produced had a uniform silver film adhering tightly on the rubber surface of the catheter (microscopically, silver powder was

uniformly attached).

(Working Example 2)

After constructing a catheter with crude rubb r, it was brought to semi-hardness to 75 % with a heat treatment. This catheter in a semi-hardened condition was soaked in catheter surface treatment solution consisting of 2 normal NaOH + 25 v o 1% C_2H_5OH to incorporate hydrophilic groups onto the surface of the catheter, then using Brashear method (3.5 g silver bromide + the appropriate amount of ammonium hydroxide + 2.5 g sodium hydroxide + 45 g dextrose + 4 g tartrate + 100 ml alcohol + 1000 ml water) about 0.4 um of silver was attached to the surface of the catheter. Next, a heat treatment was given until the desired hardness was obtained. The resultant catheter had a thick silver film and at the same time did not inhibit the original softness of the catheter.

(Working Example 3)

With a heat treatment, a catheter constructed with silicon resin was hardened to 70 %. This semi-hardened catheter was masked except the tubing portion which would go into the human body, and soaked into silver mirror reaction treatment solution consisting of 3.5 g silver bromide + appropriate amount of ammonium hydroxide + 1.2 ml 38 % formaldehyde + 45 g dextrose + 4 g tartrate + 95 ml alcohol + 105 ml water) to form a silver layer of about 0.3 um thickness on the surface of the tubing portion of the catheter. Then another heat treatment was applied until a desired hardness was obtained.

Catheters produced by any of the above mentioned methods all possessed a uniform silver film tightly adhering to the surface of the resin (microscopically silver powder uniformly attached), therefore, they do not adversely stimulate the human body upon insertion or injure the body cavities, yet, there was no infection during a long term insertion in a human body due to the bacteria reducing or bactericide ability of silver ions.

(Effectiveness of the Invention)

As described above, with this invention it is possible to produce a cathet r with a silv r film possessing a bactericide or bacteria reducing ability on the portion of the catheter which goes into a human body, enabling insertion without stimulation, and preventing infection due to the bactericide ability of silver; in addition to providing comfort to patients at the time of insertion due to the extreme thinness of the silver film, and reducing the steps for infection prevention such as the frequent washing of the urinary canal, it can be manufactured more cost effectively as compared to the conventional catheters which are teflon coated with an attachment of a metal with a bactericide and bacteria reducing ability.